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Nicholas J. Seay  
Quarles & Brady LLP  
1 South Pinckney Street  
P.O. Box 2113  
Madison, WI 53701-2113

EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/955,367

**Applicant(s)**

ATTIE ET AL.

**Examiner**

Diana B. Johannsen

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 7-11 is/are pending in the application.
- 4a) Of the above claim(s) 4,7,9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,8 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **FINAL ACTION**

1. This action is in response to the Amendment and Response including a complying complete set of claims filed March 3, 2005. Claims 1, 5, 8, and 11 have been amended, claims 2-3 and 6 have been canceled, and claims 4, 7 and 9-10 remain withdrawn from consideration. Claims 1, 5, 8 and 11 are now under consideration. Applicants' amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restriction***

3. It is again noted that claims 4, 7, and 9-10, and genes and combinations other than those elected (as noted in the prior Office action of April 8, 2004), are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the Response of April 11, 2003.

### ***Specification***

4. As stated in the prior Office action of April 8, 2004, the use of the trademark GENEARRAY has been noted in this application. The trademark should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

### ***Claim Objections***

5. Claims 1, 5, 8 and 11 are objected to because of the following informalities.

All of claims 1, 5, 8, and 11 use the term "gene(s)" when referring to proteins. For example, claim 1 refers to "any of the genes selected from the group consisting of" and recites a list including the names of proteins (e.g., rather than recited "the gene encoding cytochrome c oxidase subunit VIIa," the claim recites the name of the protein as if it were a gene). Correction is required.

The first line of claim 1 recites "diagnosis of susceptibility diabetes" rather than, e.g., "diagnosis of susceptibility to diabetes."

Additionally, as claim 1 has been amended such that it now recites multiple steps, line 2 should read "the steps of" rather than "the step of."

In claim 5, at line 6, the phrase "selected from" appears twice.

Claim 5, at lines 8-9, recites "expression pattern of the gene being decrease expression" rather than "expression pattern of the gene being decreaseded expression." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

6. In view of the cancellation of claims 2-3 and 6, the rejections of those claims under 35 USC 112, first and second paragraphs, set forth in the prior Office action are moot.

Art Unit: 1634

7. Claims 1, 5, 8, and 11 are rejected under 35 U.S.C. 112, first paragraph, for reasons set forth in the prior Office action of April 8, 2004. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The response traverses the rejection on the following grounds. Applicants argue that the mouse models described in the specification "are a normal animal model used to be a predictive disease model for diabetes" and that "It is well known that the phenomenon of increasing insulin resistance is a trait of individuals who are susceptible to, or are in the process of becoming, Type II diabetics." While acknowledging that the work described in the specification was done with mice, the Applicants urge that the mouse model "is a commonly used model for the progression from normal individual to insulin insensitive diabetes." The response further argues with regard to the SREBP gene that "it is the current belief in the art that a change in lipogenic capability in adipose tissues is indicative of a change to insulin resistance." Applicants also note that the claims have been "altered to make it clear that a 'susceptibility to diabetes' or a 'transition from obese to diabetic' is the object of each of the methods of the claims."

Applicants' arguments have been thoroughly considered but are not persuasive for the following reasons. While Applicants' response includes statements that the mouse models employed in the specification are "normal" and "commonly used" models for diabetes and diabetes progression, Applicants have not, e.g., provided any evidence that this is the case, or cited any prior art references establishing, e.g., that data obtained using their models correlates with findings in humans. In order to establish a

Art Unit: 1634

broader scope of enablement, it would be necessary to, e.g., provide actual evidence that gene expression in the models used correlates with gene expression in humans; mere statements that, e.g., a model is "commonly used" are not evidence. Further, the fact that it is well known that insulin resistance is related to diabetes or progression to diabetes does not establish a relationship between decreased expression of a group of genes in obese mice and the levels of expression of those same genes in diabetic mice, diabetic humans, etc. It is again noted that the genes of the claims were not included in Table 3 of the specification (i.e., in the Table reciting genes associated with diabetic disease), and that the specification itself states that "only 10% of individuals who are obese are diabetic" (p. 2). Finally, while it may in fact be a "current belief in the art that a change in lipogenic capability in adipose tissues is indicative of a change to insulin resistance," it remains that Applicants have not provided evidence in any form that establishes an actual association between expression of the genes of the claims and diabetes susceptibility, prognosis, predisposition, etc. Thus, Applicants' arguments are not persuasive, and this rejection is maintained.

8. Claims 1, 5, 8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons stated below and in the prior Office action.

Claims 1, 5, and 11 remain indefinite over the recitation of the molecule "aa667872 described as similar to ubiquinol-cytochrome c reductase core protein 2" in the claims. As stated in the prior Office action, it is unclear how one could identify such

Art Unit: 1634

a molecule (which is not provided with a precise structural or functional description, or described by a well-known gene name) without detecting a particular sequence that corresponded to one of the recited accession numbers at the time the invention was made. Database accession nos. are updated periodically, and therefore do not provide a clear and definite structural description of a particular molecule. Accordingly, clarification is required, and this rejection is maintained.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS' AMENDMENTS:**

Claim 1 is indefinite over the recitation of the phrase "diagnosing the individual as susceptible to diabetes if the expression of these genes is decreased as compared to other individuals." First, it is noted that the claim previously requires only "determining the expression" of "any of the genes" of the claim; thus, it is not clear whether decreased expression of "any of" the genes of the claim or (alternatively) decreased expression of "these genes" (i.e., all of the genes of the claim) would be required to meet the requirements of the claim. Further, the use of the term "other individuals" renders the claim indefinite, as it is not clear whether this language is intended to refer to, e.g., "normal," non-diabetic individuals (i.e., individuals "other than" those who are susceptible to diabetes), or whether anyone who could be considered an "other" individual would be encompassed by the claim. Thus, clarification is required with regard to how one would determine that expression is "decreased" within the context of the invention.

Claim 5 is indefinite over the recitation of the limitation “the expression pattern of the gene being decrease [sic] expression in the individual.” It is unclear what would constitute decreased expression within the context of the invention – does this refer to, e.g., decreased expression as compared to a control individual or group, decreased expression in the individual over a period of time, etc.? Clarification is required so as to apprise one of skill in the art as to how the presence of “decreased expression” is to be ascertained.

Claim 8 is indefinite over the recitation of the phrase “the decreased level of expression of the gene SREBP being indicative of susceptibility to diabetes.” First, there is insufficient antecedent basis for the limitation “the decreased level of expression.” Second, as noted above with regard to claim 5, it is unclear what would constitute decreased expression within the context of the invention – does this refer to, e.g., decreased expression as compared to a control individual or group, decreased expression in the individual over a period of time, etc.? Clarification is required.

Claim 11 is indefinite over the recitation of the phrase “a decrease in expression of those genes being associated with the transition from obese to diabetic.” First, as in claim 1, it is noted that the claim previously requires only “determining the expression” of “any of the genes” of the claim; thus, it is not clear whether decreased expression of “any of” the genes of the claim or (alternatively) decreased expression of “those genes” (i.e., all of the genes of the claim) would be required to meet the requirements of the claim. Second, it is unclear what would constitute decreased expression within the context of the invention – does this refer to, e.g., decreased expression as compared to



Art Unit: 1634

a control individual or group, decreased expression in the individual over a period of time, etc.? Third, it is not clear how determining a “decrease in expression.... associated with the transition from obese to diabetic” relates to the preamble of the claim, which recites a method “for the diagnosis or prognosis of obesity, incipient obesity, or the transition from obese to diabetic.” It appears that the steps of the claim merely result in determination of a decrease “associated with the transition from obese to diabetic,” rather than achieving the objectives set forth in the claim preamble. Thus, clarification with regard to how the steps of the claim achieve the objective thereof is also required.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1634

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Diana B. Johannsen  
Primary Examiner  
Art Unit 1634  
May 18, 2005